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No. 95-754

In The

Supreme Court of the United States

October Term, 1995

CORRECTED COPY

MEDTRONIC, INC.,

Petitioner,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Eleventh Circuit

RESPONSE TO PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state-law tort claims to recover for injuries caused by a defective medical device?

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Respondents Lora Lohr and Michael Lohr hereby respond to the petition for a writ of certiorari filed by petitioner Medtronic, Inc. The petition seeks review of a ruling of the United States Court of Appeals for the Eleventh Circuit concerning injuries suffered by Ms. Lohr at the hands of petitioner's allegedly defective cardiac pacemaker lead. The court of appeals held that respondents' claims based on defective design of the medical device were not preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*

The issues presented in the petition have deeply divided the courts of appeals, as well as other federal and state courts. As the petition indicates, ten of the federal courts of appeals have addressed the question of MDA preemption,

and the prevailing situation is one of chaos. Thus, respondents agree with petitioner that review should be granted to resolve those issues and to provide clarity for the courts, medical device manufacturers, and consumers.

In addition, the court of appeals held that respondents' state-law claims based on an alleged breach of the common-law duty-to-warn and on manufacturing defects in petitioner's pacemaker lead were preempted by the MDA. The Eleventh Circuit's rulings on those claims are the subject of the Lohrs' cross-petition for a writ of certiorari, filed herewith. *See Lohr v. Medtronic, Inc.*, No. 95-___ (filed December 6, 1995). The cross-petition explains in detail that the deepening split among the circuits concerns legal issues that are present in all three claims ruled on by the Eleventh Circuit, and shows that a grant of certiorari on both the petition and the cross-petition will allow this Court to examine all of these issues, including the courts of appeals' divergent views on the proper interpretation of the Food and Drug Administration's MDA preemption regulations. *See* 21 C.F.R. § 808.1(d), *discussed in* cross-petition at 20-22. Further, granting both this petition and the cross-petition will afford respondents the opportunity to litigate their entire case, if the Court holds that none of their claims are preempted.

CONCLUSION

For the reasons stated above, and explained in detail in respondents' cross-petition, the petition for a writ of certiorari and the corresponding cross-petition for a writ of certiorari should be granted.

Respectfully submitted,

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December 6, 1995